

Drug Information Sheet("Kusuri-no-Shiori")

External

Revised: 02/2023

The information on this sheet is based on approvals granted by the Japanese regulatory authority. Approval details may vary by country. Medicines have adverse reactions (risks) as well as efficacies (benefits). It is important to minimize adverse reactions and maximize efficacy. To obtain a better therapeutic response, patients should understand their medication and cooperate with the treatment.

Brand name: Flumetholon ophthalmic suspension 0.02%

Active ingredient: Fluorometholone

Dosage form: white ophthalmic suspension when shaken, 5mL, (bottle) clear and colorless, (cap) pale gray

Imprint or print on wrapping:



Effects of this medicine

This medicine is a synthetic adrenocortical hormone (steroid) preparation and suppresses eye inflammation by anti-inflammatory and anti-allergic effect.

It is usually used to treat eye inflammatory disease such as blepharitis, conjunctivitis, and keratitis.

The following patients may need to be careful when using this medicine. Be sure to tell your doctor and pharmacist.

- If you have previously experienced any allergic reactions (itch, rash, etc.) to any medicines or foods.
If you have: corneal epithelial abrasion, corneal ulcer, viral conjunctival/corneal disease, or tuberculous/fungal/suppurative eye disease.
- If you wear contact lenses.
- If you are pregnant or breastfeeding.
- If you are taking any other medicinal products. (Some medicines may interact to enhance or diminish medicinal effects. Beware of over-the-counter medicines and dietary supplements as well as other prescription medicines.)

Dosing schedule (How to take this medicine)

- Your dosing schedule prescribed by your doctor is((to be written by a healthcare professional))
- In general, shake the bottle well, and apply 1 to 2 drops at a time, 2 to 4 times a day. The dosage may be adjusted according to your age or symptoms. Strictly follow the instructions.
- If you are a child patient (especially less than 2 years old), you should especially follow your doctor's instructions.
- Before applying, wash your hands thoroughly with soap and running water. Next, shake the bottle well and open the cap. Then, pull down your lower eyelid lightly and apply the medicine. Be careful not to touch the dropper tip to your eyelid, eyelashes, or eye. After applying, keep your eyes closed without blinking for a while (1 to 5 minutes), and apply gentle pressure to your tear ducts (located in the inner corners of the eyes) with your fingertips. Wipe off any excess liquid gently with clean gauze or a tissue. If you need to apply other eye drops at the same time, apply other eye drops first and then wait more than 5 minutes before applying this medicine.
- If you miss a dose, apply the missed dose as soon as possible. If it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. You should not apply two doses at one time.
- If you accidentally apply more than your prescribed dose, consult with your doctor or pharmacist.
- Do not stop applying this medicine unless your doctor instructs you to do so.

Precautions while taking this medicine

Possible adverse reactions to this medicine

The commonly reported adverse reactions include stinging eyes and delayed healing of wound. If any of these symptoms occur, consult with your doctor or pharmacist.

The symptoms described below are rarely seen as initial symptoms of the adverse reactions indicated in brackets. If any of these symptoms occur, stop taking this medicine and see your doctor immediately.

- (continued use) eye pain, headache, focus disorder [glaucoma]
- eye pain, lacrimation, focus disorder [corneal herpes, keratomycosis, pseudomonas aeruginosa infection, corneal perforation]
- (long-term use) focus disorder [posterior subcapsular cataract]

The above symptoms do not describe all the adverse reactions to this medicine. Consult with your doctor or pharmacist if you notice any symptoms of concern other than those listed above.

Storage conditions and other information

- Keep out of reach of children. Store at room temperature (1 to 30 degrees Celsius) away from direct sunlight and moisture.
- Discard the remainder. Do not store them. If you do not know how to discard of it, please ask your pharmacy or medical institution on how to discard them. Do not give it to others.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.